

REMARKS

All references to page number, line numbers, and SEQ ID NO:s refer to those page numbers, line numbers, and SEQ ID NO:s, as they appear in the instant application as originally filed, unless otherwise indicated.

Status of the Claims

By virtue of the Listing of Claims presented herein, claims 30-40 are pending. Claims 1-29 and 41-51 have canceled as directed to non-elected subject matter, without prejudice or disclaimer to pursue non-elected subject matter in one or more continuing or divisional applications.

Claim 30 has been amended to remove from Step A. the phrase, “or an immunogenic fragment thereof, immunogenic derivative thereof, or immunogenic analog thereof”, and to include the word “and” after the semicolon that appears at the end of the recitation for Step A, in order to enhance clarity.

The amendments are made without prejudice or disclaimer to pursue non-elected subject matter in one or more continuing or divisional applications. No new matter has been introduced by the amendments to the claims.

Claim Rejections

Rejection under 35 U.S.C. § 112, first paragraph:

Claims 30-40 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that, whereas “[c]laim 30 has been amended to recite ‘an ob polypeptide, an immunogenic fragment thereof, an immunogenic derivative thereof, or an immunogenic analog thereof’... the specification fails to provide a written description of ‘derivatives or analogs’ of an ob polypeptide in the specification in such a way as to reasonably convey to skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” The Examiner continues, quoting *Vas-Cath In. v. Mahurkar*, 19 USPQ2d 1111: “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date

sought, he or she was in possession *of the invention*. The invention is, for the purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (outstanding Office Action, page 4, lines 10 through 13; emphasis in original).

In this regard, Applicant notes that “*whatever is now claimed*”, with respect to the claims as they appeared as rejected in the instant Office Action, is not the recited ‘derivatives or analogs’ but rather, for example, methods for measuring the recited ob polypeptides, or immunogenic fragments thereof, immunogenic derivatives thereof, or immunogenic analogs thereof. More particularly, the claimed methods comprise methods of measuring such materials in a sample, comprising: A. contacting a sample suspected of containing an ob polypeptide, an immunogenic fragment thereof, an immunogenic derivative thereof, or an immunogenic analog thereof, with an antibody that binds to an epitope of said ob polypeptide, immunogenic fragment thereof, immunogenic derivative thereof, or immunogenic analog thereof, said epitope having an amino acid sequence set out in SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:5, or SEQ ID NO:6, or an immunogenic fragment thereof, immunogenic derivative thereof, or immunogenic analog thereof, under conditions which allow for the formation of reaction complexes comprising the antibody and said ob polypeptide, immunogenic fragment thereof, immunogenic derivative thereof, or immunogenic analog thereof; and B. detecting the formation of said reaction complexes in the sample; in which detection of the formation of reaction complexes indicates the presence of said ob polypeptide, immunogenic fragment thereof, immunogenic derivative thereof, or immunogenic analog thereof in said sample. (see, e.g., Claim 30, as rejected).

Thus, ob polypeptides, or immunogenic fragments thereof, immunogenic derivatives thereof, or immunogenic analogs thereof that are measured by practicing the claimed methods possess an epitope that is complexed with the recited antibody upon contact with such antibody, forming the recited complexes.

In this regard, Applicant notes that the instant specification discloses four exemplary such amino acid sequences, which each possess such epitope(s) to which an antibody binds in order to generate the reaction complexes as recited in the rejected claims, and which are disclosed to have been introduced into rabbits in order to generate antisera containing antibodies raised against such epitope(s) (see, e.g., instant application as filed, page 64, lines 15 through 26; and SEQ ID

NO:s). Applicant further notes that these four exemplary sequences, and the epitope(s) possessed by them, span the majority of the full-length mature, circulating, leptin amino acid sequence (e.g., compare each of SEQ ID NO:s 18, 19, 20, and 21 with amino acids 22 through 167 of each of SEQ ID NOs: 2, 4, 5, and 6, independently, all as originally filed). Thus, the Examiner's contention that in the specification "there is no structure recited, except that the protein should be about 145 amino acids long," is erroneous; the application clearly discloses and describes a representative number of amino acid sequences, which sequences span essentially the entirety of full-length, mature, circulating leptin, and which sequences each possess epitope(s) as recited in the claimed methods. The skilled artisan would readily appreciate Applicant's disclosure as demonstrating possession of the claimed methods in accordance with the requirements of Section 112, first paragraph. Accordingly, the Section 112, first paragraph rejection is in error and should be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph:

Claims 30-40 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner alleges that "the instant claims are directed to methods of measuring the presence of 'an ob polypeptide, an immunogenic fragment thereof, an immunogenic derivative thereof, or an immunogenic analog thereof' in a sample using an antibody that binds to the polypeptide, fragment, derivative or analog." Again, as explained above, the Examiner has misconstrued the claims. The claimed methods as currently rejected, and as instantly presented, recited that recited antibody binds to an epitope of said ob polypeptide, immunogenic fragment thereof, immunogenic derivative thereof, or immunogenic analog thereof, said epitope having an amino acid sequence set out in SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:5, or SEQ ID NO:6. Thus, an ob polypeptide, an immunogenic fragment thereof, an immunogenic derivative thereof, or an immunogenic analog thereof that is complexed to such an antibody is so complexed by virtue of the presence of such an epitope. Again, as explained above, such epitopes are sufficiently described and disclosed in the instant application. Therefore, the claimed methods are sufficiently definite and distinct so as to satisfy the

requirements of Section 112, second paragraph. Accordingly, the Section 112, second paragraph, rejection is erroneous and should be withdrawn.


Conclusion

Applicants believe that all issues raised in the Office Action have been properly addressed in this response and in the amendments to the claims as shown in the attached Listing of Claims. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants' representative at the telephone number below.

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Deposit Account 19-4293 referencing Docket No. 16454.0002 D2. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Deposit Account 19-4293.

Respectfully submitted,

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